



## Informed Consent Penile Implant

This information is given to you so that you can make an informed decision about having penile implant **surgery**.

### Reason and Purpose of the Procedure:

Penile implants are devices placed inside the penis to allow men with erectile dysfunction (ED) to get an erection. Penile implants are typically recommended after other treatments for ED fail. Penile implants can also be used to treat severe cases of a condition that causes scarring inside the penis, leading to curved, painful erections (Peyronie's disease).

There are two main types of penile implants: semi-rigid and inflatable.

- The three-piece inflatable penile implant consists of inflatable cylinders inside the shaft of the penis. A fluid reservoir is placed under the abdominal wall and a pump inside the scrotum.
- The two-piece inflatable penile implant consists of inflatable cylinders inside the shaft of the penis. A combined fluid reservoir and pump unit is placed in the scrotum.
- The semi-rigid penile implant can be bent upward for sex. It can be bent toward the body for concealment under clothing.

**Benefits of this surgery or procedure:** You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Improve erectile function
- Improve penile curvature

### Risks of Surgery or procedure:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

### General risks of surgery or procedure:

- Small areas of the lungs may collapse. This would increase the risk of infection. This may need antibiotics and breathing treatments.
- Clots may form in the legs, with pain and swelling. These are called DVTs or deep vein thrombosis. Rarely, part of the clot may break off and go to the lungs. This can be fatal.
- A strain on the heart or a stroke may occur.
- Injury to organs, blood vessels, and/or nerves can occur. This could be found during the surgery or after the surgery. This could need further surgery or treatments to repair.
- Bleeding may occur. If bleeding is excessive, you may need a transfusion.
- Reaction to the anesthetic may occur. The most common reactions are nausea and vomiting. In rare cases, death may occur. The anesthesiologist will discuss this with you.

Patient Name:

DOB:

**Risks of this surgery or procedure:**

- **Infection.** As with any surgery, infection is possible. You might be at an increased risk of infection if you have a spinal cord injury or diabetes. You may need antibiotics. In severe cases surgery may be needed to remove, repair or replace the implant.
- **Implant problems.** Implants are reliable, but in rare cases the implants might fail. Surgery may be needed to remove, repair or replace a broken implant.
- **Internal erosion or adhesion.** In some cases, an implant might stick to the skin inside the penis or wear away the skin from inside the penis. Rarely, an implant breaks through the skin. These problems are sometimes linked to an infection.
- **Loss of sensation at the tip of the penis.** You might need more medications or treatments to repair.
- **Inability to place device due to anatomy or mechanical issues.** You might need additional surgery.
- **Injury to adjacent tissue.** This may cause inflammation and difficulty passing urine. A tube may need to be put into the bladder to drain the urine. This is usually temporary until the bladder recovers.
- **Shortening of penile shaft.**

**Risks associated with smoking:**

Smoking is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

**Risks associated with obesity:**

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

**Risks specific to you:**

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**Alternative Treatments:**

Other choices:

- Oral drugs or medications
- Vacuum Erection Devices (VED)
- Testosterone Therapy (when low testosterone is detected in blood testing)
- Penile Injections (ICI, intracavernosal Alprostadil)

**If you choose not to have this treatment:**

- Your erectile dysfunction symptoms may continue or worsen.
- Talk to your provider about your treatment options.

**General Information:**

- During this procedure, the doctor may need to perform more or different procedures than I agreed to.
- During the procedure the doctor may need to do more tests or treatments.
- Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.
- Students, technical sales people and other staff may be present during the procedure. My doctor will supervise them.
- Pictures and videos may be done during the procedure. These may be added to my medical record. These may be published for teaching purposes. My identity will be protected.
- Implants/explants statement: I agree to release my name and address, and my date of birth to the company that makes the medical device that is put in or removed during this procedure. Federal laws and rules require this. The company will use this information to contact my provider.
- You will receive an implant card. One side gives instructions on how to use implant. The other side provides you with implant serial number and MRI compatibility.
- My insurance company may not pay for this device or procedure. I know I am responsible for charges not covered by my insurance.

Patient Name: \_\_\_\_\_

DOB: \_\_\_\_\_

**By signing this form I agree:**

- I have read this form or had it explained to me in words I can understand.
- I understand its contents.
- I have had time to speak with the doctor. My questions have been answered.
- I want to have this procedure: **Penile implant**  *three piece inflatable*  *two piece inflatable*  *semirigid*  
\_\_\_\_\_
- I understand that my doctor may ask a partner to do the surgery.
- I understand that other doctors, including medical residents, or other staff may help with surgery. The tasks will be based on their skill level. My doctor will supervise them.

**Provider:** This patient may require a type and screen or type and cross prior to surgery. If so, please obtain consent for blood/products.

Patient Signature \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

Relationship:  **Patient**       **Closest relative (relationship)** \_\_\_\_\_       **Guardian**

**Interpreter's Statement:** I have translated this consent form and the doctor's explanation to the patient, a parent, closest relative or legal guardian.

Interpreter: \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_

Interpreter (if applicable)

**For Provider Use ONLY:**

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Provider signature: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

**Teach Back**

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Patient shows understanding by stating in his or her own words:

\_\_\_\_ Reason(s) for the treatment/procedure: \_\_\_\_\_

\_\_\_\_ Area(s) of the body that will be affected: \_\_\_\_\_

\_\_\_\_ Benefit(s) of the procedure: \_\_\_\_\_

\_\_\_\_ Risk(s) of the procedure: \_\_\_\_\_

\_\_\_\_ Alternative(s) to the procedure: \_\_\_\_\_

**OR**

\_\_\_\_ Patient elects not to proceed: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

(Patient signature)

Validated/Witness: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_